UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
	)	Subcategory No. 06-CV-11337
THIS DOCUMENT RELATES TO:	)	Hon. Patti B. Saris
United States of America, ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06–CV-11337-PBS	)	

UNITED STATES' REPLY TO ABBOTT LABORATORIES, INC.'S RESPONSE TO AMENDED STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF UNITED STATES' MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO ABBOTT LABORATORIES INC.'S MOTION FOR SUMMARY JUDGMENT

The United States hereby submits its Reply to Abbott's Response to its Amended Statement of Undisputed Material Facts Applicable to the Abbott Laboratories, Inc., in Support of its Motion for Partial Summary Judgment (Abbott's Rule 56.1 Response).

PRELIMINARY STATEMENT

The United States submits this Reply to Abbott's Responses to the United States' Amended Statement of Fact to assist the Court by demonstrating that there is in truth no real dispute with respect to the core material facts asserted by the United States in support of its motions for summary judgement.[1] The Government is not addressing the responses where Abbott has admitted the facts[2] or responded with an assertion of additional fact that, on its face, does not raise a material issue with respect to the truth or accuracy of a statement asserted by the United States.

As an initial matter, nothing in Abbott's Rule 56.1 individual responses create a genuine dispute of material fact. Further, Abbott repeatedly asserts throughout its Response that the United States' record citations do not provide support for the assertions for which they are cited. This is not true. Indeed, nearly all of the United States' facts are derived from the nearly verbatim cited testimony, or quotations from documents. Moreover, in support of many of its responses, Abbott failed to file exhibits at all; Abbott provided record support that is clearly not supportive of the proposition (by citing to, for example, to incorrect pages).

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[1] The United States adopts the abbreviation conventions set forth in footnote 1 of Defendants' Combined Response to the United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants. The United States' Responses to Abbott's Rule 56.1 Statement of Additional Fact are referenced herein as "US Resp ABT SOAF ¶__".

[2] For the United States Statements of Fact ("US-A-SF") numbered 4, 11, 16, 37, 43, Abbott does not dispute these statements of fact and the underlying record support, and they should deemed admitted pursuant to Local Rule 56.1 for summary judgment purposes. While Abbott does not dispute the US-A-SF Nos. 1, 2, 3, 4, 5, 9, and 13. Abbott does provide qualification to in its responses to these statements. Abbott's qualifications, however, do not provide factual information or support to contest or negate the record support provided by the United States, or suggest that these statements are disputed. Accordingly, these statement should be deemed admitted pursuant to Local Rule 56.1 as well.

GENERAL REPLIES

1. Abbott has inappropriately attempted to dispute facts which were asserted by the United States solely for the purpose of disputing facts asserted by Abbott in support of their motions for summary judgment. The federal rules do not provide for the type of responses stated by Abbott, which, in any event, do nothing to resolve any issue in its favor.

2. Abbott's objections that certain of the paragraphs in the United States' Local Rule 56.1 Statement include expert opinion, and for that reasons should be disregarded, is improper. Abbott has attacked the damage calculations of the United States' expert, Mark Duggan, Ph.D. in the motions for summary judgment. *See* Abbott's *Daubert* motion, Dkts 6175, 6177. Thus, the United States and its expert must be allowed to respond to those attacks. Additionally, witnesses such as Mr. Ormond and Mr. Dew are not expert witnesses, but rather summary witnesses who compiled and summarized significant amounts of data and documents in an organized fashion for the Court's ease finding and identifying certain information.

3. Abbott does not actually dispute the facts in many of the paragraphs of the United States' Local Rule 56.1 Statement. As just one example, in response to US-A-SF ¶68, Abbott denies the statement that Abbott HPD adopted a new pricing guideline for setting list prices at "5% above its actual WAC". But, Abbott's response confirms that Abbott does not dispute that under Abbott's practice developed after 2000, HPD list prices were "set approximately 5% over the Wholesale Acquisition Cost." These types of responses raise distinctions without differences. To a great extent, Abbott's responses simply argue that other inferences could be drawn from the undisputed facts. However, the inferences suggested by Abbott largely pertain to

immaterial semantics and, in any event, are also argued in defendants', including Abbott's, legal briefs. The underlying facts are not affected by these semantics.

4. Abbott cannot use its Rule 30(b)(1) testimony of its employees to negate Abbott's corporate testimony through its Rule 39(b)(6) witnesses. Significantly, the Rule 30(b)(6) testimony for Abbott occurred in February and March of 2008 at the very close of discovery. The Rule 30(b)(6) testimony of Michael Sellers concluded on the last day of fact discovery in this case March 31, 2008. Similarly, David Fishman, Abbott's in-house lawyer, was deposed on March 12 and 20, 2008 as a Rule 30(b)(6) witness for compliance-related matters. Both Mr. Fishman and Mr. Sellers had ample opportunity to review the Rule 30(b)(1) deposition testimony of Abbott's employees to ascertain whether their testimony fits squarely with the corporation's factual positioning, and to explain any inconsistencies. Abbott cannot now try to contradict or challenge facts supported by its own corporate testimony with fact witness testimony that the corporate representatives could have, or in some instances did, review and take into account in providing the corporate factual knowledge and position.

5. In its various responses, Abbott repeatedly asserts that the "Government knew full well that the compendia AWPs were not representative of actual market prices. . ." This is directly contradicted by Abbott's own documents evidencing its extensive lobbying efforts by Medicare Working Group member David Landsidle, among others. (*See* US Resp ABT SOAF ¶ 82)

6. With respect to testimony concerning and from state and federal officials, the United States adopts herein the US Resp to Combined SOAF, including 91.1 to 91.9 and the extensive references by the United States to federal witness testimony. Under *United States v.*

Lachman, 387 F.3d 42, 54-55 (1st Cir. 2004), the non-public or informal understandings of agency officials concerning the meaning of agency regulations are not relevant to interpreting the regulations.

SPECIFIC REPLIES TO ABBOTT'S RESPONSES TO CERTAIN OF THE UNITED STATES' STATEMENTS OF UNDISPUTED FACT

Reply to Abbott Response to US-A-SF ¶ 7 & 8:

Abbott offers no record support to dispute this factual assertion. Abbott's Vancomycin historical document expressly provides that "Abbott's Vancomycin market share was 37% in hospital and 60% in alternate site businesses in 1996, the last year Vancomycin was approved for Medicare reimbursement". Sellers Rule 30(b)(6) Exh. 27. In his testimony, Mr. Sellers merely says that he subjectively reads the document differently. He offers no testimony that refutes the fact Abbott's admission in the document that by 1996 had 60 percent of the vancomycin *market share*.

Reply to Abbott Response to US-A-SF ¶ 12:

Abbott disputes this statement, but offers no record support to oppose its own Answer to the Amended Complaint, and its witness confirmed the statement. Moreover, the record support from Ms. Leone's deposition only supports the factual proposition that Abbott had a provider agreement with HCFA and the requisite provider number. Otherwise, Abbott's wholly-owned pharmacies would have been unable to bill Medicare and Medicaid.

Reply to Abbott Responses to US-A-SF ¶ 14 - 18:

Abbott's objection regarding the timeliness of the Duggan Declaration should be overruled. Abbott has not identified any new material in the declaration which primarily

summarizes Dr. Duggan's expert report provided to Abbott in June 2008. Abbott then conducted a *five-day* long deposition of Dr. Duggan spread out over the course of 10 months from July 2008 to June 2009. Abbott's blanket dispute of "all factual statements made in Dr. Duggan's declaration" is abusive and should be ignored.

Abbott's dispute regarding Abbott's average transaction prices calculated by Dr. Duggan fails to raise a genuine issue of fact. Abbott's expert, Steven Young, did not "detail" any errors in the calculations of Abbott's average prices by Dr. Duggan and did not even calculate any competing average prices. Tables 1 to 10 of Dr. Duggan's expert report demonstrate that he evaluated $3.45 billion of Abbott direct sales and $876 million of indirect sales in connection with his calculation of Abbott's average transaction prices using data supplied by Abbott. (Duggan Expert Report, Abbott Exh. DT). Dr. Duggan then focused on specific classes of trade that paid approximately 20% more than the overall average price, thereby reducing damages by that amount to Abbott's obvious benefit. In contrast, Mr. Young simply presented conclusory statements regarding theoretical sales at an "unknown price" to unknown customers. Mr. Young's report doesn't identify any actual customer, transaction or price for these unknown sales to unknown customers of his own client. In sum, Mr. Young has failed to identify any actual factual basis for his conclusions and Abbott's position on this point is without factual support.

Reply to Abbott Responses to US-A-SF ¶¶ 19-28, 73, 74, 80:

Abbott has not identified any actual error in Mr. Ormond's declaration. In para. 27, Abbott states that it would have used a different label for one of the columns in one of the appendices, but it in no way alleges that the difference would have impacted the underlying facts in any substantive manner.

Abbott's objection that Mr. Ormond's testimony is inadmissible expert testimony should be overruled. Mr. Ormond does nothing more than summarize existing data. The primary thrust of Mr. Ormond's affidavit was his creation of spreadsheets, and charts based on those spreadsheets, which simply gather together in one place the prices for the Subject drugs that were listed in Abbott's own catalogs, in the Redbook, in the First DataBank ("FDB") data files and in Dr. Duggan's expert materials, all of which was produced to Abbott in discovery. For some charts, Mr. Ormond used *division* to show that the AWP published by Red Book and FDB were almost universally 18.75% higher than the corresponding prices appearing in Abbott's own catalogs. Mr. Ormond's declaration is squarely within F.R.E 1006 ("The contents of voluminous writings, records, or photographs which cannot conveniently be examined in court may be presented in the form of a chart, summary, or calculation.) *See Peat, Inc. v. Vanguard Research*, Inc. 378 F.3d 1154 (11th Cir. 2004).

Reply to Abbott Response to US-A-SF ¶ 29:

Abbott disputes US-A-SF ¶29 without providing any contrary record support. US-A-SF ¶29 is a verbatim quote from a document that Abbott's own Rule 30b6 witness admits was the definition of AWP that Abbott HPD had always used. Sellers 30(b)(6), 3/16/08 at 261:3-22; 262:1-14. Moreover, Abbott's own Additional Statement of Fact supports this statement (Abbott's Statement of Additional Fact 30), which Abbott supports by citing Sellers 30(b)(6), 3/16/08 at 261 & 262.

Reply to Abbott Response to US-A-SF ¶ 30:

Abbott disputes US-A-SF ¶30 without providing any contrary record support. Moreover, the record support properly cited by the United States is derived from Abbott's own Rule

30(b)(6) witness, who testified as follows:

> Q. Well, then, was it Abbott's understanding that the provision of AWP information could in part be considered spread marketing because it provides a component of the information that the client could use to calculate the spread?
>
> MS. CITERA: Object to the form, outside the scope.
>
> BY THE WITNESS:
>
> A. It was one essential component of spread marketing.
>
> Q. Okay. So the provision of AWP information, Abbott understood was one of the essential components of spread marketing?
>
> MS. CITERA: Objection to the form, outside the scope.
>
> BY THE WITNESS:
>
> A. To my knowledge, yes.

(Fishman 30(b)(6), 3/20/08 at 674; 675 1-6) The questions posed to Mr. Fishman plainly are not hypothetical.

Reply to Abbott Response to US-A-SF ¶ 31:

Abbott disputes US-A-SF ¶31, but yet admits that at least some employees did know that there was or may have been a relationship between AWP and Medicare and Medicaid reimbursement. The United States did not state that *all* of Abbott's thousands of employees knew about the relationship. Accordingly, the record evidence cited by Abbott does not dispute or controvert US-A-SF ¶31.

Reply to Abbott Response to US-A-SF ¶ 32:

Abbott disputes US-A-SF ¶32 without providing any contrary record support to contradict the testimony of its own witness. The deposition testimony cited by Abbott does not dispute either US-A-SF ¶32 as they pertain to the understanding of witnesses and employees other than

Ms. Snead. These witnesses also do not negate the knowledge of the entire sales force, as Abbott itself appears to acknowledge.

As the record support cited by the United States provides, a National Accounts Manager (NAM), Ms. Snead testified:

> Q. And what is average wholesale price?
> A. It's -- I know that it was something that is used -- that our customers used in part for reimbursement.
> Q. How did you know that it was something that your customers used for reimbursement?
> A. That was just common knowledge.
> Q. It was common knowledge among the Abbott sales representatives that Abbott's customers used AWP for reimbursement?
> MS. GEISLER: Objection to the form.
> A. Yes. I think it was common knowledge to anybody in the market.

Snead Dep at 72:3-15.

> * * * *

> Q. Were you aware -- let me ask you this question: When you were within Alternate Site Product Sales as a national account representative and then a NAM, did you have an understanding as to how the AWP for Abbott's drugs was selected?
> A. No.
> Q. You said you knew that customers used AWP as a reimbursement -- that it was somehow related to reimbursement, right?
> A. Yes.
> Q. Did you understand that the customers who purchased Abbott's drugs and dispensed those drugs to patients were generally reimbursed by some third-party payer, such as private insurance or government insurance program?
> A. Yes.
> Q. Okay. And did you also understand that

government insurance programs, such as Medicare and Medicaid, generally reimbursed on the basis of AWP minus a percentage?

MS. GEISLER: Objection to the form.

A. I understood that AWP was involved in the reimbursement, but I didn't know the detail.

Q. (BY MR. WINTER) You didn't know the specifics. But did you have a general understanding that it was AWP minus some percentage?

MS. GEISLER: Objection to the form

A. All I knew is that AWP was somehow used in reimbursement, but I didn't know anything about the percentage part.

Q. (BY MR. WINTER) Okay. You just knew it was a factor in the reimbursement and that reimbursement was somehow keyed off of AWP, right?

MS. GEISLER: Objection to the form.

A. Yes.

Q. (BY MR. WINTER) Okay. And -- and, again, that's something that you testified was common knowledge within the market, right?

MS. GEISLER: Objection to the form.

A. Yes.

Snead Dep. 73-74.

* * *

Q. (BY MR. WINTER) And can you think of any other reason why the customer would want that AWP information other than to do an analysis on the reimbursement spread?

MS. GEISLER: Objection to the form.

A. No.

Snead Dep. at 124

On its face, this testimony supports the factual statement set forth in US-A-SF ¶32. The depositions cited by Abbott in response to this Statement of Fact only serve to provide information concerning the understanding of those employees testifying and do not negate Ms.

Snead's testimony concerning her understanding. Abbott cannot contest the materiality of Ms. Snead's testimony simply because of the period of time that has elapsed since she left the company. Ms. Snead was a National Account Manager for Abbott during at least a portion of the operative 1991 to 2001 time period of this case.

Reply to Abbott Response to US-A-SF ¶ 33 & 34:

Abbott disputes US-A-SF ¶33 & 34, without providing any contrary record support to contradict the testimony of its own witness. The deposition testimony cited by Abbott does not dispute either US-A-SF ¶ 33 as they pertain to the understanding of witnesses and employees other than Mr. Heggie. Mr. Heggie testified:

> Q. So the spread would be the difference between the reimbursement amount, whether it is Medicare or Medicaid reimbursing and the sale price; correct?
> MS. CITERA: Objection to form.
> THE WITNESS: Well, yes, but you are way off in what you are trying to do. Medicaid rebates here have nothing to do with AWP.
>
> Heggie 5/17/07 Dep. at 40:11-13.
>
> * * *
>
> Q. Can you remind me again when you became a manager of reimbursement within Alt Site?
> A. No, I don't know. I don't remember. But it was -- all of my time was in Alternate Site, from the time I started at Abbott, so when I became a manager, I don't really remember. Probably '93, maybe.
>
> Heggie 5/17/07 Dep. at 48:1-16.
>
> * * *

A. In other words, there is some evidence that, often, the AWP for a drug is set at a particular level to establish third-party reimbursement –

MS. CITERA: I'm going to object to the form. Sorry.

THE WITNESS: But has no relevance to any party beyond the third party payor. Well, I would have trouble with the fact that AWP is set. For example, I don't believe that AWP -- and you can see this from my other testimony. I don't believe that AWP is set. AWP is a function of list.

Heggie 5/17/07 Dep. at 156:7-19.

* * *

Q. So would you agree, then, that the AWP for a drug is relevant to the pharmacies, to insurance companies, to Medicare and the Medicaid programs?

A. Sure.

Q. Would you agree with whoever these unnamed people are within the industry that said AWP makes little sense as a basis for reimbursement as of 1996?

MS. CITERA: Objection to form.

THE WITNESS: Sure.

BY MR. GOBENA:

Q. Why?

A. Because it is senseless. It was an antiquated system that made no sense for anybody to be working off.

Heggie 5/17/07 Dep. at 162:1-11.

* * *

Q. And you talked earlier about how you understood that the price reporting compendia added on an 18.75 percent markup to the list to publish

-- and then published an AWP that reflected that.
Do you recall that testimony?
A. I do, and that was -- it was Redbook who had that formula. We were talking at that point about Redbook. I don't know the formula that MediSpan and BlueBook, which I think BlueBook later became First DataBank, I think, but I don't recall. I don't know that I ever knew their formulas. The only formula I actually -- but it was basically about 20 percent. When theirs came out, theirs was basically about 20 percent.
Q. And you recall in one of the documents that we looked at earlier about this Medicaid Drug Rebate Program AMP restatement issue. There is a sentence in a memo that you wrote that said there is a discrepancy between list price and sales

Heggie 5/17/07 Dep. at 165:4-22.

* * *

price.
Do you remember that?
A. Yeah.
Q. So you knew there was a discrepancy between list price and sales price; correct?
MS. CITERA: Objection, form.
THE WITNESS: There was an internal discrepancy, yes, I knew it was in the calculation.
BY MR. GOBENA:
Q. List price was one thing, and the sales price was another thing; correct?
A. Correct, right.
Q. And the list price -- did you know that the list price was higher than the sales price?
A. Well, of course.
Q. Of course it was, right?
A. Yeah.
Q. And the list price was then being used -- was then being used by the price reporting compendia to come up with the published AWP; is that correct?
A. That's correct.

Heggie 5/17/07 Dep. at 165:4-22; 166:1-22.

* * *

Q. So why did you think it was senseless?
A. I thought it was senseless because everyone knew that it was not the most economical way to pay for drugs or to pay for whatever they were marking up.
Q. And why was it not the most economical way for, let's take Medicare, to be paying for drugs that used AWP as a basis for reimbursement for drugs?
A. Because of the way the calculation came about for the AWP.
Q. And that calculation was based on list price; correct?
A. Correct.
Q. And list price was significantly higher than sales price for these drugs; correct?
MS. CITERA: Objection to form.

Heggie 5/17/07 Dep. at 168:6-22.

* * *

THE WITNESS: Correct.

Heggie 5/17/07 Dep. at 169:1.

* * *

Q. And that's consistent with your testimony that Abbott knew Redbook information, including AWPs, was transmitted to Medicaid and Medicare programs; correct?
MS. CITERA: I object to the form.
THE WITNESS: Yes, correct.

Heggie 5/17/07 Dep. at 219:3-8.

The depositions cited by Abbott in responses to US-A-SF 33 & 34 only serve to provide information concerning the understanding of those employees testifying, and do not negate Mr.

Heggie's testimony concerning his understanding. Abbott cannot contest the materiality of Mr. Heggie's testimony simply because of the period of time that has elapsed since he left the company. Mr. Heggie was an Alternate Site Reimbursement Manager for Abbott during at least a portion of the operative 1991 to 2001 time period of this case.

Reply to Abbott Response to US-A-SF ¶ 35 & 36:

Abbott disputes US-A-SF ¶ 35 & 36, without providing any contrary record support to contradict the testimony of its own witness. The deposition testimony cited by Abbott does not dispute either US-A-SF ¶ 35 or 36 as they pertain to the understanding of witnesses and employees other than Mr. Brincks. Abbott also appears to concede the substance of most of US-A-SF ¶ 35 & 36. Plainly on its face, the record support correctly cited by the United States provides ample support for the stated facts concerning Mr. Brincks.

The depositions cited by Abbott in response to US-A-SF ¶ 35 & 36 only serve to provide information concerning the understanding of those employees testifying, and do not negate Mr. Brincks' testimony concerning his own understanding. Abbott cannot contest the materiality of Mr. Brincks' testimony as Mr. Brincks was an Alternate Site Contract Marketing manager for Abbott during at least a portion of the operative 1991 to 2001 time period of this case.

Reply to Abbott Response to US-A-SF ¶ 38:

Abbott disputes US-A-SF ¶38, without providing any contrary record support to contradict the testimony of its own witness concerning that witness' knowledge. Notably, the testimony of the witnesses Abbott cites were not directly involved with the Home Infusion business unit, as Mr. Brincks was, but rather were familiar with Abbott's Alternate Site customers.

Reply to Abbott Response to US-A-SF ¶ 39, 40, 41, 42 , 44, 45, 46:

Abbott claims to dispute this US-A-SF ¶ 39, 40, 41, 42, 44, 45 & 46 even though they are plainly supported by the record citations provided by the Government, including most notably its own Rule 30(b)(6) corporate representative testimony. Abbott offers no testimony that counters these specific statements. Abbott also appears to concede the virtually the entirety statements in its responses when providing its explanations of its objections. Moreover, HBS employees responsible for setting prices, who are cited in ¶ 39, 40, 41, 42, 44, 45 & 46 *are HPD Abbott employees*. HBS was not a separate legal entity prior to 2003.

Reply to Abbott Response to US-A-SF ¶47.

Abbott offers no record evidence to dispute this statement, and appears to concede its content in the response. Abbott's objection to this undisputed statement is unavailing as *Abbott's* practices in reporting pricing to the compendia are relevant to this case. The fact that Abbott in its HPD division for 1991 to 2001 reported highly inflated list prices to the compendia, causing the publication of inflated AWPs and spreads from 113 to 1637 percent, but did not engage in the same conduct within PPD, is telling and highly dispositive. Abbott offers no alternative calculations for the spreads between its published AWPs and wholesale market prices from 1991 to 2001. Further, Abbott's objections to the use of material relating to its PPD should be overruled because the Court has previously ruled that all "cross-cutting" documents relating to AWP spreads are relevant to the issues in this case. (Docket #4244).

Other than for its Erythromyin products, Abbott's PPD division reported pricing with far lower spreads and pricing that more accurately reflected its PPD marketplace prices. PPD's list price formulaic equivalent was WAC, plus 5%. Moreover, the fact that when Abbott decided to

lower its prices in 2001, it turned to the model of its PPD division evidences, in part, Abbott's understanding that it should have reported pricing to the compendia that was moored in its transactional pricing.

Reply to Abbott Response to US-A-SF ¶48.

Abbott claims to dispute this US-A-SF ¶48, even though it is plainly supported by the record citation provided by the Government, including most notably its own Rule 30(b)(6) corporate representative testimony. Mr. Sellers, as Abbott's representative, unequivocally testified:

> Q. Now, these inadvertent disparities that you identified for some products where there was a large gap between the contract prices and the catalog prices --
>
> A. Yes.
>
> Q. -- was there an HBS business reason for the existence of those inadvertent disparities?
>
> MS. TABACCHI: Object to the form.
>
> THE WITNESS: No.

(US-A-SF ¶ 48)

Reply to Abbott Response to US-A-SF ¶60:

As the record citation from the United States makes clear, Mr. Sellers testified that were some products where there was a "significant difference". (Sellers 30b6, 3/16/08 at 53:1-22; 54:1-7). Contrary to Abbott's assertion, this testimony is supportive of and not contrary to the statement of fact.

Reply to Abbott Response to US-A-SF ¶62:

Abbott's objection that Mr. Dew's testimony is inadmissible expert testimony should be overruled. Mr. Dew does nothing more than summarize existing data. The primary thrust of Mr. Dew's affidavit is to briefly summarize Abbott's own transactions. Abbott has identified no prejudice resulting from Mr. Dew's brief summary of its own transactions. Nor has Abbott identified any inaccuracies in Mr. Dew's affidavit. Abbott's assertion that Mr. Dew's analysis identified sales at or above AWPs rather than list price is completely unsupported by any factual basis whatsoever and may be disregarded. In addition, Mr. Dew's declaration is squarely within F.R.E 1006 ("The contents of voluminous writings, records, or photographs which cannot conveniently be examined in court may be presented in the form of a chart, summary, or calculation.) *See Peat, Inc. v. Vanguard Research*, Inc. 378 F.3d 1154 (11th Cir. 2004).

Reply to Abbott Response to US-A-SF ¶118:

Abbott improperly attempts to hide behind attorney-client privilege on a business operations matter. *See* Reply to Abbott Response to US-A-SF ¶ 121-129 below.

Reply to Abbott Response to US-A-SF ¶119

As set forth in the documents filed as St. Peter-Griffith Dep. Exh. 12, members of the Medicare Working Group, including David Landsidle, communicated and were involved with Abbott's lobbying efforts. *See* US Resp. ABT SOAF ¶ 82.

Reply to Abbott Response to US-A-SF ¶ 121 - 129

The United States denies that matters pertaining to the Abbott's measures to stay compliance with federal law are privileged. Abbott attempts to shield itself improperly in privilege for matters that are directly pertinent to its pricing and price reporting conduct.

Moreover, Abbott admits that Mr. Tootell testified that he raised his concerns about the propriety of Abbott's price reporting practices with in-house counsel. Abbott offers no evidence to contradict this. Given Abbott's in-house counsel's role in business matters, including the involvement of counsel in Abbott's efforts to preclude the inclusion in the BBA of discretion for the Secretary, Abbott's in-house counsel were considerably involved in AWP and compliance related *business* matters. That involvement was nowhere more apparent than in the fact that Abbott produced its own in-house attorney, David Fishman, as its Rule 30(b)(6) representative on compliance matters, from whose testimony the United States derived much of its record support for these undisputed statements of fact. *See United States ex rel Parikh v. Premera Blue Cross*, 2006 WL 3733783, *5 (W.D. Wash., Dec. 15, 2006)(because in-house counsel may play a dual role of legal advisor and business advisor, the privilege will apply only if the communications primary purpose is to gain or provide legal assistance).

Reply to Abbott Response to US-A-SF ¶70:

Abbott's objection to this undisputed statement is improper. Abbott's knowledge of AWPs and the relationship between its list price reporting and the calculation of those AWPs by the compendia is highly material. Abbott fails to explain why for nearly all of its PPD products, it elected to play by the rules, but flouted the rules for its HPD products.

Reply to Abbott Response to US-A-SF ¶87:

The United States incorporates herein US Resp. ABT SOAF ¶¶ 42, 45, & 48.

Reply to Abbott Response to US-A-SF ¶130 & 131:

Abbott disputes these statements on the grounds that they are irrelevant. The fact that Abbott's joint venturer partner, TAP, pled guilty and entered into a corporate integrity agreement with the government for, among other acts, marketing the spread, should inform the Court's

decision-making on issues related to Abbott's purported lack of understanding of AWP and the impact of its price reporting conduct. As a condition of resolving TAP's criminal and civil liability, Abbott was a required signatory to a letter agreement consenting to TAP's criminal, civil and administrative resolutions. (US-A-SF Par. 131). Notably, as reflected in the record provided by the United States for US-A-SF 130 and 131, Abbott's in-house counsel in 1987 authored a brief and participated in a lawsuit involving TAP. In that action, TAP sued to keep in place its AWP for Medicare reimbursement. Abbott in-house counsel's knowledge about AWP matters, and their calculation for Medicare purposes, is also highly relevant, particularly given that Abbott appears to disavow knowledge of the fact that list price is the formulaic equivalent of AWP, and the impact of inflated list prices on Medicare and Medicaid reimbursement.

Moreover, contrary to Abbott's assertion that this Court has determined the TAP case irrelevant, this Court has recognized the relevance of Abbott's role in TAP AWP-related matters when it ordered: "TAP shall produce all documents expressly referencing Abbott or directly involving Abbott personnel" relating to AWP/government reimbursement issues or AWP spread marketing from 1991 to 2003. (MD #4701)

Reply to Abbott Response to US-A-SF ¶132-145:

With respect to the United States' statements of fact pertaining to the operation of Abbott's Home Infusion business unit, Abbott seeks to strike these facts as improper and untimely. These are undisputed *evidentiary* facts. Abbott is confusing complaint pleading matters with powerful evidence of its conduct and scienter. (*See* US Resp. ABT SOAF ¶ 15)(US-A-SF ¶¶ 132-146). For the $232 million in claims directed to Medicare and Medicaid, Abbott caused the submission under the FCA by directly submitting the false claims, which is the exact same conduct and transactions set forth in Ven-A-Care's complaint.

Respectfully submitted,

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Dated: September 22, 2009

I hereby certify that I have this day caused an electronic copy of the above UNITED STATES' REPLY TO ABBOTT LABORATORIES, INC.'S RESPONSE TO AMENDED STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF UNITED STATES' MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO ABBOTT LABORATORIES INC.'S MOTION FOR SUMMARY JUDGMENT to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Mark A. Lavine

Dated: September 22, 2009 Mark A. Lavine